IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No.: ____________________
	)	
ACTAVIS ELIZABETH LLC,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Orexo AB and Orexo US, Inc. ("Orexo US") (collectively, "Plaintiffs"), for their Complaint against defendant Actavis Elizabeth LLC ("Actavis Elizabeth" or "Defendant"), hereby allege as follows:

THE PARTIES

1. Plaintiff Orexo AB is a company organized and existing under the laws of Sweden, having its principal place of business at Virdings allé 32 A, 754 50 Uppsala, Sweden.

2. Plaintiff Orexo US is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 150 Headquarters Plaza, East Tower, Morristown, New Jersey 07960. Orexo US is a wholly owned subsidiary of Orexo AB.

3. On information and belief, defendant Actavis Elizabeth is a company organized and existing under the laws of the state of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United

States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338.

5. This Court has personal jurisdiction over Actavis Elizabeth. Actavis Elizabeth is a Delaware company. It is registered with the Delaware Department of State: Division of Corporations under file number 0875422 and maintains a registered agent for service of process in Delaware.

6. On information and belief, Actavis Elizabeth regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Actavis Elizabeth has continuous and systematic contacts with Delaware.

7. On information and belief, Actavis Elizabeth is in the business of manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the state of Delaware. On information and belief, Actavis Elizabeth directly or through its affiliates and agents develops, formulates, manufactures, markets, and/or sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district.

8. On information and belief, Actavis Elizabeth holds an active Delaware pharmacy wholesale license (No. A4-0000069) and an active Delaware controlled substances distributor/manufacturer license (No. DS0751).

9. On information and belief, Actavis Elizabeth has availed itself of this forum by consenting to personal jurisdiction and/or asserting counterclaims in other civil actions initiated in this jurisdiction, including but not limited to *Cephalon, Inc. v. Actavis LLC et al.*,

14-cv-122-GMS (D. Del. 2014) and *Janssen Pharms., Inc. v. Actavis Elizabeth LLC, et al.*, 13-cv-04507-CCC-JAD (D. Del. 2013).

10. Actavis Elizabeth has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

11. On information and belief, upon approval of Actavis Elizabeth's Abbreviated New Drug Application (ANDA) No. 206258 and its Amendment, Defendant and/or its affiliates or agents will market and sell Actavis Elizabeth's Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate Sublingual Tablets, Eq. 1.4 mg/0.36 mg Base and Eq. 5.7 mg/1.4 mg Base (the "ANDA Products") in Delaware and throughout the United States and will derive substantial revenue therefrom. On information and belief, upon approval of Actavis Elizabeth's ANDA and its Amendment, Defendant and/or its affiliates or agents will sell the ANDA Products in the state of Delaware and throughout the United States and will be involved in the manufacture, distribution, and/or marketing of the ANDA Product.

12. On information and belief, upon approval of Actavis Elizabeth's ANDA and its Amendment, Defendant and/or its affiliates or agents will place the ANDA Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in this judicial district.

13. On information and belief, this Court further has personal jurisdiction over Defendant because Defendant regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware and committed the tortious act of patent infringement

under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to plaintiff Orexo US, a Delaware corporation.

14. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, the above-mentioned facts.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENT-IN-SUIT

16. Orexo US holds approved New Drug Application ("NDA") No. 204242 for buprenorphine hydrochloride and naloxone hydrochloride sublingual tablets, which are prescribed and sold in the United States under the trademark Zubsolv®.

17. Zubsolv® sublingual tablets are indicated for the maintenance treatment of opioid dependence and for the induction of buprenorphine maintenance therapy in patients suffering from opioid dependence.

18. United States Patent No. 9,439,900 ("the '900 patent," copy attached as Exhibit A) is titled "Abuse-Resistant Pharmaceutical Composition for the Treatment of Opioid Dependence" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on September 13, 2016. The '900 patent claims, *inter alia*, pharmaceutical compositions containing buprenorphine and naloxone. The '900 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Zubsolv® sublingual tablets (NDA No. 204242).

19. The named inventor of the '900 patent is Andreas Fischer. The '900 patent is assigned to Orexo AB.

CLAIMS FOR RELIEF - PATENT INFRINGEMENT

20. Actavis Elizabeth submitted an Amendment to ANDA No. 206258 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products.

21. On information and belief, the Amendment to ANDA No. 206258 seeks FDA approval of the ANDA Products for the indication of maintenance treatment of opioid dependence and/or for the induction of buprenorphine maintenance therapy in patients suffering from opioid dependence.

22. By letter dated November 14, 2016, and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95, Actavis Elizabeth notified Plaintiffs that it had submitted an Amendment to ANDA No. 206258 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the ANDA Products before the expiration of the ’900 patent.

23. In its November 14, 2016 letter, Actavis Elizabeth notified Plaintiffs that, as a part of its Amendment to the ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”) with respect to the ’900 patent.

COUNT I
Infringement of U.S. Patent No. 9,439,900 Under 35 U.S.C. § 271

24. Plaintiffs repeat and reallege paragraphs 1 through 23 as if fully set forth herein.

25. By submitting the Amendment to ANDA No. 206258 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products throughout the

United States prior to the expiration of the ’900 patent, Actavis Elizabeth committed an act of infringement of the ’900 patent under 35 U.S.C. § 271(e)(2).

26. The commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, for which Actavis Elizabeth seeks approval in the Amendment to ANDA No. 206258, will infringe, induce infringement, and/or contributorily infringe one or more claims of the ’900 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

27. Actavis Elizabeth’s ANDA Products will have the same clinical instructions on use, be administered in the same manner, and achieve the same results as Zubsolv® sublingual tablets. Actavis Elizabeth’s Proposed ANDA Products label will instruct doctors, caregivers, and/or patients to practice one or more of the methods claimed in the ’900 patent.

28. Defendant was aware of the ’900 patent at the time the Amendment to the ANDA was submitted and deliberately and intentionally submitted the Amendment to the ANDA with knowledge that one or more claims of the ’900 patent covered the ANDA Products or their use.

29. Plaintiffs will be irreparably harmed by Defendant’s infringing activities and do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendant and respectfully request the following relief:

A. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendant has infringed one or more claims of the ’900 patent by submitting the Amendment to ANDA No. 206258 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products before the expiration of the ’900 patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of the ANDA Products will infringe the ’900 patent under 35 U.S.C 271(a), 271(b), and/or 271(c).

C. A judgment declaring that the ’900 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Defendant and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products until the expiration of the ’900 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

E. An order that the effective date of any approval of Actavis Elizabeth’s ANDA No. 206258, as amended, under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the ’900 Patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

F. A determination that this case is “exceptional” under 35 U.S.C. § 285 and an award of attorneys’ fees;

G. Costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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